

# The Nanotechnology Characterization Laboratory (NCL)

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# NCI Alliance for **Nanotechnology** in Cancer

- NCI's Nanotech Efforts
  - Unconventional Innovations Program (UIP)
  - Cancer Nanotechnology Plan
- Consensus among cancer researchers that significant obstacles must be overcome in order to transition 'nano' to clinical realm
  - Critical lack of available standards
  - 1<sup>st</sup> principles characterization
  - Regulatory uncertainty

# Nanotechnology Characterization Laboratory

## Mission Statement

- The Nanotechnology Characterization Laboratory (NCL) will perform and standardize the pre-clinical characterization of nanomaterials developed by researchers from academia, government, and industry.
- The NCL will serve as a national resource and knowledge base for cancer researchers, and facilitate regulatory review and translation of nanomaterials and devices into the clinical realm.



# NCL Objectives

- Identify and characterize critical parameters related to nanoparticles' absorption, distribution, metabolism, excretion, and acute toxicity (ADME/Tox) in animal models; structure-activity relationships.
- Establish and standardize an assay cascade for nanomaterial characterization that facilitates regulatory review of nanodevices for cancer clinical trials.
- Examine the biological characteristics of multi-component/combinatorial aspects of nanoscaled therapeutic, molecular and clinical diagnostics, and detection platforms.
- Engage and facilitate academic and industrial-based knowledge sharing of nanomaterial performance data and behavior resulting from pre-clinical testing.

# NCL Concept of Operations

## Sources of Nanomaterials

Cancer Centers of Nanotech Excellence (CCNEs)

Academia

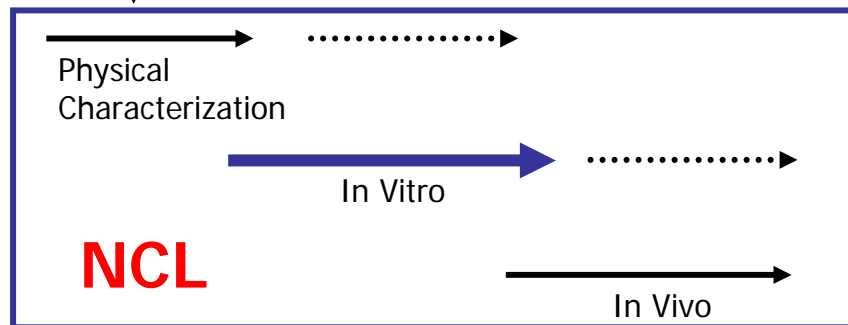
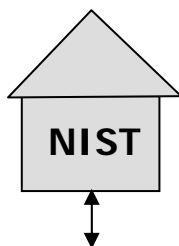
NNI

Small Business


NCI, NIH, NSF

DoD, DoE

Unconventional Innovative Program (UIP)



**NCL facilitates the 'apples to apples' comparison and characterization of nanomaterials intended for cancer detection, diagnostics, and therapeutics in humans.**



# Physical Characterization

## Property

- Size, Size Distribution, MW, Density
- Surface Area, Porosity
- Hydrophilicity, Surface Charge Density
- Purity
- Sterility
- Surface Chemistry
- Stability

## Instrumentation

- Zetasizer, SEM/TEM, Dynamic Light Scattering, AFM, Hydrometer, Pycnometer
- Gas Adsorption, AA
- Zetasizer
- FTIR, GC-MS, FPLC, NMR
- BacT Lab Analysis
- Chemistry Lab, FTIR
- Methods Above

**Physical characterization will be conducted in collaboration with NIST.**



## ***In Vitro Assays***

### **Property**

- Binding and Pharmacology →
- Blood contact →
- Cellular uptake →
- Toxicity, *in vitro* ADME →

### **Assay/Instrumentation**

ELISA, Flow Cytometry,  
Fluorescence Microscopy,  
Surface Plasmon Resonance,  
Liquid Scintillation Counter

Chromatography, HPLC, Gel  
Electrophoresis

Fluorescence Microscopy, SEM,  
Electrophoresis

Microscopy, spectroscopy, HPLC,  
Liquid Scintillation,  
Electrophoresis

# *In Vivo* Assays (Animal Models)

## Property

- Efficacy
- Initial Range Finding Pharmacology
- Acute Toxicity
- Biodistribution Pharmacokinetics
- Hemodynamics



## Method

*In Vitro* Assays + Histopathology,  
Clinical Chemistry, Hematology

- Image contrast



MRI, Ultrasound, PET

**Intent is to conduct structure-activity characterization and to develop a standardized assay cascade that addresses safety and acute toxicity.**



# NCL's Interaction w/ the US FDA

- NCI-FDA Interagency Oncology Task Force
  - Nanotechnology subcommittee
    - Addresses translational issues unique to nanotech
- Input into the design of NCL's assay cascade
- FDA representative sits on NCL's technical advisory board
- NCL intends to influence the '*scientific quality of data submitted*' to FDA in the Investigative New Drug (IND) application.



# Interaction w/ NCL

- Interaction w/ NCL is a collaboration
  - NCL will seek extensive input from you prior to characterizing your material
  - Anticipate at least two data reviews during characterization
- NCL is NOT a funding source
  - Characterize existing nanotech strategies
  - There is no charge to researchers for characterization by NCL
- Assay cascade will take 12 to 18 months
- Resulting Data
  - NCL data is intended to be included in an investigator-led filing of an IND application.



# Interaction w/ NCL

- Scope of Nanoparticles
  - Multifunctional and less than 100nm in at least one dimension
  - Liposomes, dendrimers, QDs, carbon-based, etc.
  - Not desired: biologics (e.g. viral particles) or nanostrategies intended for *in vitro* purposes only.
- Intellectual Property
  - NCL assumes submitters have already secured their IP
  - Characterization will be conducted under a Materials Transfer Agreement (MTA)
  - **Fine Print:** Data generated by NCL will be made available to public following a 60-day quiet period.
    - Delay allows submitters to further secure IP
    - NCL will NOT disclose your confidential/proprietary info



# Application Process

- Solicitation to be published in Feb '05
  - NCL will accept proposals from academia, industry and government
- Proposal:
  - White paper (3-4 pages)
  - Full proposal (<20 pages)
- Evaluation criteria
  - Demonstrated efficacy in a biological system
  - Impact on cancer research, previous characterization, transition plan



# Summary

- NCL's role in the Alliance
  - Conducts pre-clinical characterization
  - Facilitates regulatory review
- NCL is a national resource
  - CCNEs, academia, industry, government
  - No cost to cancer researchers
- Solicitation will be published in Feb '05
  - Website <http://nano.cancer.gov>
  - Email: [NCL@ncifcrf.gov](mailto:NCL@ncifcrf.gov)